

REMARKS

This amendment is responsive to the Office Action dated September 13, 2006. Claims 1 - 18 are pending in this application and have been rejected. Reexamination is respectfully requested in view of the foregoing amendments and following remarks.

These remarks follow the order of the detailed Office Action beginning at page 2 thereof.

Correction in Specification

During preparation of this response, Applicant found that there is an error on page one at line 14. Therefore, Applicant has amended "obtained by 1-electron-reducing" to "obtained by 2-electron-reducing". This change is consistent with lines 14 and 15 of page 1 of the specification and is further based upon lines 20 - 24 of the specification. The use of the language "1-electron-reducing" is obviously a clerical error and should have been "2-electron-reducing". Still further, the original specification, original claims and new claims all refer to 2-electron reduced which is consistent with the change in the specification.

Claim Rejections - 35 USC § 112

Pending claims 1 - 18 were rejected as being generally

narrative and indefinite. In response, Applicant has canceled claims 1 - 18 in their entirety and has presented for examination new claims 19 - 22.

To assist the Examiner in understanding the new claims, Applicant presents herein below a copy of new claim 19 with references to Applicant's Figure 4 and 6 which teaches the method of quantifying as claimed.

19. A method of quantifying coenzyme Q-10 and a 2-electron reduced form thereof contained in a specimen, comprising the steps of:

extracting said coenzyme Q-10 and 2-electron reduced form thereof from said specimen using a water-soluble organic solvent selected from the group consisting of isopropyl alcohol and a solvent having a polarity comparable to that of isopropyl alcohol, so as to obtain an extraction liquid which contains extracted coenzyme Q-10 and 2-electron reduced form thereof;

concentrating **16** said extracted coenzyme Q-10 and 2-electron reduced form thereof using a concentration column **16** and a first mobile phase, so as to obtain concentrated coenzyme Q-10 and 2-electron reduced form thereof;

separating **18** said concentrated coenzyme Q-10 and 2-electron reduced form thereof using a separation column **18** and a second mobile phase which is different from said first mobile phase, so as to obtain separated coenzyme Q-10 and 2-electron reduced form

thereof;

reducing 20 said separated coenzyme Q-10 using a reduction column 20; and

detecting 22, 24 said reduced coenzyme Q-10 and said separated 2-electron reduced form using a detector.

In the rejection under 35 USC § 112, original claims 1 - 18 were rejected because they refer to coenzyme Q-10 and a 2-electron reduced form thereof. Applicant respectfully submits that this is neither vague nor indefinite. In Applicant's specification there is a description of ubiquinone of humans, etc. which is represented as coenzyme Q-10 and ubiquinol of humans, etc., which is represented as a 2-electron reduced form of coenzyme Q-10 (see lines 20 - 24 of page 1 of the specification). That is "coenzyme Q-10 and a 2-electron reduced form thereof" clearly referred to a ubiquinone and a ubiquinol, respectively. Thus, the recitation of coenzyme Q-10 and a 2-electron reduced form thereof in Applicant's claims is definite when the description of the specification is referred to. Applicant, therefore, respectfully traverses the claim rejection regarding the term "coenzyme Q-10 and a 2-electron reduced form thereof".

With respect to the objections relating to pretreatment and an analytic sample, these terms have been eliminated from the newly presented claims 18 - 22. For this reason, this rejection

has been overcome.

With respect to the phrase "a temperature within a range of a melting point of the extracted liquid and room temperature", this phrase has been changed in the pending claims (new claim 20) to "a temperature within a range of room temperature to a melting point of said extraction liquid". The Examiner has correctly noted that the melting point of the extraction liquid is a uniquely determined point. For any liquid as the Examiner notes, this is a known temperature. Still further, room temperature is a commonly accepted term and is known. Therefore, the range set forth in new claim 20 is precisely defined and the rejection has been overcome.

In the objection relating to the term "condensing", and the term "condensation", these terms have been changed to "concentrating" and "concentration" as these terms are used in the specification with respect to the description of Figure 6. In the above-copy of claim 19 (with reference numerals), these points are shown in the claim which correspond to Figure 6. The amended claims do not include the points objected to, and do include terms clearly supported by the specification.

With regard with the recitation in originally presented claims 17 and 18, new claims 21 and 22 are provided while claim 17 and 18 have been canceled. The recitations in new claims 21 and 22 are clearer than those of canceled claims 17 and 18. It is therefore respectfully submitted that the rejection of claims

17 - 18 stated in page 3, last five lines, and page 4, has been respectfully overcome.

Claim Rejections - 35 USC § 102

Original claims 1 - 16 were rejected under 35 USC § 102 (b) as anticipated by Edlund. The new claims now define over Edlund.

When the present invention, according to new claims 19 and 20, is compared with Edlund, "reducing said separated coenzyme Q-10 using a reduction column" recited in the new claims is not disclosed in Edlund. Therefore, the present invention according to new claims 19 and 20 is not anticipated by the prior art disclosed in Edlund.

Next, when the present invention according to any of new claims 21 and 22 is compared with the prior art disclosed in Edlund, "a reduction column of reducing said coenzyme Q-10 so as to obtain a reduced coenzyme Q-10" recited in our new claim 21 is not disclosed in Edlund. Therefore, the present invention according to new claims 21 and 22 is not anticipated by the prior art disclosed in Edlund.

Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. §§ 102 (b) and 103 (a) as anticipated over Grossi et al.

When the present invention, according to new claims 19 and 20, is compared with Grossi, "extracting said coenzyme Q-10 and 2-electron reduced form thereof from said specimen using a water-soluble organic solvent selected from the group consisting of

isopropyl alcohol and a solvent having a polarity comparable to that of isopropyl alcohol", "concentrating said extracted coenzyme Q-10 and 2-electron reduced form thereof using a concentration column and a first mobile phase", or "reducing said separated coenzyme Q-10 using a reduction column" in new 19 is neither disclosed nor suggested in Grossi.

In the invention, according to new claims 19 and 20, variation in the ratio of coenzyme Q-10 to 2-electron reduced form thereof can be suppressed by "extracting said coenzyme Q-10 and 2-electron reduced form thereof from said specimen using a water-soluble organic solvent selected from the group consisting of isopropyl alcohol and a solvent having a polarity comparable to that of isopropyl alcohol".

On the other hand, conventional methanol and n-hexane are used for deproteinizing plasma and 2-propanol is used not for extraction but for elution of CoQs from C₁₈ cartridge in "Method B" and "Method C" in page 219 of Grossi. Also, "2-propanol" listed in Table 1 of the "RESULTS AND DISCUSSION" of Grossi is not used for extraction solvent but is used as a solvent for elution from a cartridge. Thus, "a water-soluble organic solvent selected from the group consisting of isopropyl alcohol and a solvent having a polarity comparable to that of isopropyl alcohol" is not used for "extracting said coenzyme Q-10 and 2-electron reduced form thereof from said specimen" in Grossi.

Furthermore, although there is a description in regard to

the solubility of CoQ₁₀ in some kinds of solvents and there is a description of "the liquid - liquid extraction method (A)" in "RESULTS AND DISCUSSION" in page 220 of Grossi, there is no description for extraction solvent in the liquid - liquid extraction method (A). Also, the suppression of variation in the ratio of coenzyme Q-10 to 2-electron reduced form thereof is neither disclosed nor suggested in Grossi. Therefore, Grossi neither discloses nor suggests use of 2-propanol as an extraction solvent.

Furthermore, none of "a concentration column" and "a reduction column" is disclosed nor suggested Grossi.

In the present invention according to new claims 19 and 20, a polar impurity contained in a specimen which impurity may influence the quantification of coenzyme Q-10 and 2-electron reduced form thereof may be included in "an extraction liquid which contains extracted coenzyme Q-10 and 2-electron reduced form thereof", when "extracting said coenzyme Q-10 and 2-electron reduced form thereof from said specimen using a water-soluble organic solvent selected from the group consisting of isopropyl alcohol and a solvent having a polarity comparable to that of isopropyl alcohol". However, it makes it possible to sufficiently remove such a polar impurity contained in a specimen from "an extraction liquid which contains extracted coenzyme Q-10 and 2-electron reduced form thereof" by "concentrating said extracted coenzyme Q-10 and 2-electron reduced form thereof using

a concentration column and a first mobile phase".

On the other hand, there is no requirement of use of such "a concentration column" in the prior art disclosed in Grossi since no or few polar impurities would be mixed into conventional methanol and n-hexane used in Grossi. For this reason, there is no motivation to use "a concentration column" as described above in Grossi.

When the present invention, according to new claims 21 and 22 is compared with the Grossi prior art, "a condensation column of concentrating said coenzyme Q-10 and 2-electron reduced form thereof, when said first mobile phase with said analytical sample is fed" or "a reduction column of reducing said coenzyme Q-10 so as to obtain a reduced coenzyme Q-10" is neither disclosed nor suggested in Grossi.

In the present invention, according to new claims 21 and 22, "a condensation column of concentrating said coenzyme Q-10 and 2-electron reduced form thereof, when said first mobile phase with said analytical sample is fed" is included in order to make it possible to sufficiently remove a polar impurity contained in a specimen from an extraction liquid which contains extracted coenzyme Q-10 and 2-electron reduced form thereof where the coenzyme Q-10 and 2-electron reduced form thereof are extracted from the specimen using a water-soluble organic solvent selected from the group consisting of isopropyl alcohol and a solvent having a polarity comparable to that of isopropyl alcohol, as

mentioned above.

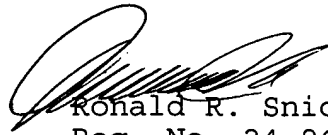
On the other hand, there is no requirement of use of such "a concentration column" in the prior art disclosed in Grossi since no or few polar impurities would be mixed into conventional methanol and n-hexane used in Grossi. That is, there is no motivation to use "a concentration column" as described above in Grossi.

Furthermore, Grossi provides no motivation to use a reduction column.

The present invention according to any of claims 21 and 22 should not be considered anticipated by or obvious from the prior art disclosed in Grossi.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action in accordance thereof is requested. In the event there is any reason why the application cannot be allowed in this current condition, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems by Interview or Examiner's Amendment.

Respectfully submitted,



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